IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

GEORGE STEVEN LEGRAND, on behalf of himself and all others similarly situated, Plaintiff, v. UNIMED PHARMACEUTICALS, INC.; SOLVAY PHARMACEUTICALS, INC.; WATSON PHARMACEUTICALS, INC.; PAR PHARMACEUTICALS, INC.; and PADDOCK LABORATORIES, INC., Defendants.	:	Case No. **CLASS ACTION COMPLAINT AND JURY DEMAND**

Plaintiff, George Steven LeGrand ("Plaintiff"), on behalf of himself and all others similarly situated, files this Class Action Complaint against Defendants, Unimed Pharmaceuticals, Inc. ("Unimed"); Solvay Pharmaceuticals, Inc. (collectively, with Unimed Pharmaceuticals, Inc.; "Solvay"); Watson Pharmaceuticals, Inc. ("Watson"); Par Pharmaceuticals, Inc. ("Par"), and Paddock Laboratories, Inc. ("Paddock") (collectively, "Defendants"). Plaintiff, upon

knowledge as to matters relating to himself and upon information and belief as to all other matters, alleges as follows:

NATURE OF THE ACTION

1. This antitrust action seeks damages resulting from Defendants' unlawful "sham" patent litigation intended to delay and exclude a generic version of the drug sold under the brand name AndroGel, a topical testosterone, from the market. AndroGel was and is marketed by Solvay as a testosterone replacement therapy ("TRT") for males with a deficiency or absence of endogenous testosterone.

2. Defendants substantially delayed the onset of generic competition of topical testosterone by orchestrating a conspiracy to initiate and participate in settling "sham" patent litigation concerning AndroGel and its generic equivalents. Among other things, Solvay (a) wrongfully listed its United States Patent No. 6,503,894 (the "'894 patent'") patent in the Food & Drug Administration ("FDA") publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book"); (b) with knowledge that its patent was incorrect, wrongfully initiated and prosecuted "sham" patent litigation against its prospective generic competitors Par, Paddock and Watson (collectively "Generic Defendants") in order to trigger the thirty month automatic stay provision of the 1984 Hatch-Waxman amendments to the Food, Drug and

Cosmetics Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman Act"), prohibiting the FDA from granting final approval to generic companies seeking to sell generic AndroGel; and (c) entered into agreements settling the "sham" litigation with Generic Defendants whereby in late 2006 Solvay agreed to pay Generic Defendants significant sums of money, as well as other forms of compensation, in exchange for Generic Defendants agreeing not to sell their generic versions of AndroGel until 2015 in the case of Watson, the first Abbreviated New Drug Application filer, and until 2016 for the other Generic Defendants.

3. Solvay knew that, under the Hatch-Waxman Act, the exclusivity of its new dosage for AndroGel was set to expire on February 28, 2003, and Abbreviated New Drug Applications ("ANDAs") seeking to market generic versions of AndroGel were likely to be filed, seeking approval for marketing, immediately thereafter. Solvay therefore tried to obtain a patent so that it could use that patent as a platform to argue that the patent covered AndroGel, before its exclusivity expired. In January 2001, Solvay obtained the '894 patent, less than two months before its exclusivity was set to expire.

4. Solvay knew at the time it submitted the '894 patent for listing in the Orange Book that it was only entitled to list the '894 patent in the Orange book if the '894 patent: (1) claimed AndroGel or an approved method of using AndroGel

and (2) a claim of patent infringement could reasonably be asserted against a person not licensed by the owner engaged in the manufacture, use, or sale of AndroGel. However, Solvay knew that the listing was improper because, *inter alia*, (a) originally issued claims 1-30 of the '894 patent (as well as the "corrected" versions of those claims) were invalid because there was no written description support for the sodium hydroxide range stated therein; and (b) none of the originally issued claims could be reasonably construed as covering AndroGel or a method using AndroGel. As described in more detail below, Solvay knew that its efforts to quickly push its '894 patent through the Patent and Trademark Office ("PTO") resulted in errors that prevented the '894 patent from covering AndroGel or an approved method of using AndroGel.

5. After listing an improper patent ('894) in the Orange Book, Solvay proceeded to file "sham" lawsuits against the Generic Defendants alleging patent infringement of the '894 patent. As demonstrated below, no reasonable litigant could have expected that Solvay's infringement lawsuits would succeed because, *inter alia*, (a) originally issued claims 1-30 of the '894 patent (as well as "corrected" versions) were not valid because there was no written description support for the sodium hydroxide range stated therein; (b) none of the originally issued claims could be interpreted as covering generic versions of AndroGel or a method of using generic versions of AndroGel; (c) even after "correcting" claims

1-30 of the '894 patent the Generic Defendants could not be viewed as infringing any of the '894 patent claims because the certificate of correction was inapplicable to patent litigation initiated prior to the certificate of correction being issued, and the certificate was invalid because Solvay made affirmative misrepresentations to the PTO in order to obtain the certificate; and (d) claim 31 and its dependant claims could not be reasonably interpreted to cover the use of the Generic Defendants' AndroGel products because Solvay deliberately excluded sodium hydroxide from claim 31, when sodium hydroxide materially affects the basic and novel properties of the invention. Solvay's knowledge that the Generic Defendants did not infringe claims 1-30 of the '894 patent, as issued, is demonstrated by the fact that Solvay filed a Request for Certificate of Correction of the '894 patent prior to filing the patent infringement suits against the Generic Defendants, and it would not have done so unless it recognized the existing patent was deficient.

6. Solvay was trying to "protect" its profits from generic competition. Brand name drugs and their generic versions contain the same active ingredient, and generics are found by the FDA to be just as safe and effective as their brand drug counterpart. The only material difference between generics and brand name drugs is their price. In those instances where there is one generic competitor, generics are usually at least 30% less expensive than their brand name counterparts. The discount usually increases to 50-80% (or higher) when multiple

generic competitors exist in the market. In fact, AB-rated generic versions of brand name drugs typically take 80% or more of the sales of the brand name drugs within the first year of generic entry.

7. Solvay filed its "sham" litigation against the Generic Defendants in order to invoke the automatic 30-month stay of FDA approval, because it knew that it would not have been able to obtain a preliminary injunction halting the Generic Defendants from launching their generic versions of AndroGel. To obtain a preliminary injunction, Solvay would have had to prove, *inter alia*, that it was likely to succeed on the merits of the patent infringement suits. Solvay knew that it could not have demonstrated a likelihood of success on the merits because its patent infringement claims against the Generic Defendants were baseless.

8. Solvay's improper listing of the '894 patent and its initiation of "sham" litigation on the '894 patent were anticompetitive and caused damages to the Plaintiff and the Class (defined below) because, *inter alia*, it prevented the FDA from approving the Generic Defendants' AndroGel products until after the automatic 30-month stays. But for the "sham" litigation, Watson would have begun marketing its generic AndroGel product upon receiving FDA approval, which would have occurred no later than January 27, 2006. Similarly, but for the "sham" litigation, Par and Paddock would have begun marketing its generic AndroGel product upon receiving FDA approval which would have occurred no

later than May 27, 2007.

9. Instead of allowing the Generic Defendants to challenge Solvay's patents at the trial of the "sham" litigation it initiated, Solvay paid the Generic Defendants millions of dollars in exchange for the Generic Defendants' agreement not to market generic AndroGel until either 2015 or 2016. Defendants mischaracterized these payments as purportedly being for: (a) licensing and co-promotion; and/or (b) back-up manufacturing of AndroGel.

10. Solvay's initiation of "sham" litigation and the subsequent settlements by the Generic Defendants reached as a result of that litigation have denied Plaintiff and other indirect purchasers of AndroGel the benefits of competition and of less expensive, generic versions of AndroGel. As a result, Plaintiff and members of the Class have suffered damage by having paid supracompetitive prices for AndroGel.

JURISDICTION AND VENUE

11. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive relief, and the costs of suit, including reasonable attorneys' fees, for injuries to Plaintiff and members of the Class resulting from, *inter alia*, Defendants' violations of the federal antitrust laws. Plaintiff also asserts claims under California law, including: violations of the California Cartwright Act, violations of the California Unfair Competition Law, and unjust enrichment.

12. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 22 and 26, 28 U.S.C. §§ 1331, 1337(a), and 1332(d)(2). This court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(a).

13. Venue is proper in this District under 15 U.S.C. §§ 15, 22, and 26, and under 28 U.S.C. § 1391, because (1) Defendants transact business and are found within this District; (2) a substantial portion of the affected trade and commerce described below has been carried out in this District; and (3) this action has been transferred to this District pursuant to an Order of the Judicial Panel on Multidistrict Litigation.

PARTIES

14. George Steven LeGrand is an adult individual residing in West Hollywood, California and purchased AndroGel during the Class Period.

15. During the Class Period, Plaintiff paid supracompetitive prices for some or all of the cost of AndroGel, which was prescribed to him, beginning January 19, 2009 and has thereby been injured as a result of Defendants' unlawful conduct.

16. Solvay Pharmaceuticals, Inc. is a Georgia corporation with its principal place of business in Marietta, Georgia. Solvay is the U.S. subsidiary of Solvay Pharmaceuticals. Together, with its wholly owned subsidiary Unimed,

Solvay develops, manufactures, and markets pharmaceuticals and related products, including AndroGel, in the United States. Solvay Pharmaceuticals, Inc. itself negotiated and/or approved Unimed Pharmaceuticals, Inc.'s relevant anticompetitive agreements concerning AndroGel, the filing and prosecution of the patent case against Par, Paddock and Watson, and has a financial interest in AndroGel.

17. Unimed is a wholly owned subsidiary of Solvay Pharmaceuticals, Inc. that develops, manufactures, and markets pharmaceuticals and related products, including AndroGel, in the United States. Unimed focuses on developing and marketing drugs in the multiple indications in the therapeutic areas of cardiology, men's health (urology and endocrinology) and certain infectious diseases.

18. Watson is a Nevada corporation with its principal place of business in Corona, California. Watson principally develops, manufactures and markets generic versions of brand name drugs.

19. Par is a Delaware corporation with its principal place of business in Woodcliff Lake, New Jersey. Par principally develops, manufactures and markets generic versions of brand name drugs.

20. Paddock is a privately-held pharmaceutical company located in Minneapolis, Minnesota. Paddock principally develops, manufactures and markets generic versions of brand name drugs.

BACKGROUND

The Regulatory System Governing Pharmaceuticals In The United States

A. New Drug Applications

21. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., ("FD&C Act"), as amended by the Hatch-Waxman Act, and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 27 1(e) (2005), establishes procedures designed to facilitate competition from lower-priced generic drugs.

22. Approval by the FDA (the governmental body charged with regulating the pharmaceutical industry) is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 355(a). Pre-market approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 355(b) of the FD&C Act demonstrating that the drug is safe and effective for its intended use.

23. New drugs that are approved for sale in the United States by the FDA are often covered by patents, which provide the patent owner with the ability to seek to exclude others from making, using, and/or selling (depending on the scope of the patent) that new drug in the United States for the duration of the patents, plus any extension of the original patent granted pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355.

24. Pursuant to 21 U.S.C. § 355(b), in its NDA, the pioneer drug manufacturer must list those patents that claim the drug for which FDA approval is being sought or that claim a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. Once the NDA is approved by the FDA, any such patents are listed with the NDA in the Orange Book.

25. Federal regulations restrict the types of patents that an NDA holder can submit to the FDA for listing in the Orange Book. *See generally* 21 C.F.R. § 314.53. One such limitation is imposed by 21 C.F.R. § 314.53(b), which explicitly prohibits NDA holders from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

26. Despite the FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has become common for brand-name pharmaceutical companies to list every patent they can obtain in the Orange Book, so as to force generic manufacturers to file what, as described below, is commonly known as a "Paragraph IV certification."

27. The FDA does not police the listing of patents, and does not use an adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing in the Orange Book. The FDA has stated that it lacks the resources and expertise to review the patents submitted to it, in connection with

NDAs.

28. As a result, the FDA's role in the patent listing process is purely ministerial, and it relies entirely upon the good faith of the NDA holder.

B. Generic Drugs

29. Generic drugs are drugs that the FDA has found to be bioequivalent to their corresponding brand name drugs. A generic drug provides identical therapeutic benefits and has the same side effects and safety profile as its corresponding brand name drug.

30. Generic drugs invariably cost substantially less than the branded drugs to which they are bioequivalent. Typically, the first generic version of a brand-name drug is sold at a substantial discount to the brand, followed by increasingly steeper discounts as more generics enter the market.

31. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand name drug with an approved NDA by filing an ANDA pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand name drug.

32. After an applicant has submitted its ANDA to the FDA it must file a patent certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii). Four types of patent certifications are available:

a. The brand-name manufacturer has not filed patent information with the FDA (a "Paragraph I certification");

b. The patent or patents listed in the Orange Book have expired (a "Paragraph II certification");

c. The patent will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration (a "Paragraph III certification"); or

d. The patent is invalid or not infringed by the generic manufacturer's product (a "Paragraph IV certification"). *See* 21 U.S.C. § 355(j)(2)(A)(vii).

33. A generic drug applicant must serve the brand-name drug company with a copy of any certification under Paragraph IV. The Paragraph IV certification constitutes a "technical act of infringement" under Hatch-Waxman which creates jurisdiction in the federal courts to entertain a patent infringement action and gives the NDA holder forty-five days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If such a suit is initiated, the FDA's approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

34. Because of this thirty month stay, the mere filing of an infringement action in response to a Paragraph IV certification, regardless of the action's underlying merit, gives the brand-name company the functional equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without the brand company's ever having to establish likelihood of success on the merits, irreparable harm, that the balance of hardships tips in its favor, or that the public good is served by the blocking of entry.

35. An improper Orange Book listing has additional anticompetitive effects, because the first generic company to file an ANDA with a Paragraph IV certification is, upon FDA approval, granted a 180-day period of marketing exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day exclusivity period is awarded to the first Paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV certification. Absent an improper Orange Book listing, no Paragraph IV certification would be required and, thus, no generic company would receive 180-day exclusivity. Instead, multiple generic competitors would enter the market simultaneously.

36. Defendants were at all times fully familiar with their ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Act.

The Consumer Benefits Of Generic Drugs

37. Upon their introduction, generic drugs generally enter the market at prices 30% to 50% (or more) below the price of their brand-name equivalents. Because generic and branded drugs are fully interchangeable in terms of safety and efficacy, the vast majority of patients are switched to the less expensive generic in place of the brand-name drug.

38. Almost all states (and the District of Columbia) encourage generic competition through laws that allow pharmacists to substitute brand-name drugs with their "AB-rated" generic equivalents, unless a physician directs or the patient requests otherwise.

39. Many third-party payors of prescription drugs (*e.g.*, health insurance plans, Medicaid programs) have adopted policies to encourage the substitution of available AB-rated generic drugs for their branded counterparts.

DEFENDANTS' ANTICOMPETITIVE CONDUCT AND "SHAM" LITIGATION

Solvay's Prosecution Of The '894 Patent

40. The hormone, testosterone, which is contained in AndroGel, is unpatented. Patents covering the synthesis of artificial testosterone expired many years ago.

41. AndroGel is a brand name drug marketed by Solvay and used for

replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. AndroGel is indicated to treat those men with primary hypogonadism and hypogonadotropic hypogonadism. Low testosterone levels are often associated with advancing age, certain cancers, diabetes and HIV/AIDS.

42. AndroGel is a topically applied gel formulation of testosterone, which provides for a controlled release of testosterone into the bloodstream. AndroGel's generic name is testosterone topical.

43. In August, 1995, Solvay licensed the U.S. rights to the testosterone gel formulation used for AndroGel from the Belgian pharmaceutical company Besins Healthcare, S.A. (together with its affiliates "Besins"), which had developed the formulation. At that time, Besins agreed to supply Solvay with AndroGel after the product was approved for sale by the FDA. Even after accounting for expenses related to marketing AndroGel, Solvay sells AndroGel at prices significantly higher than what it pays Besins, and AndroGel is very profitable for Solvay.

44. On August 30, 2000, Solvay filed with the PTO United States Patent Application Serial No. 09/651,777 ("the '777 Application"). The '894 patent issued from the '777 Application on January 7, 2003. Upon information and belief, Solvay and Besins jointly owned the '777 application and jointly own the

‘894 patent.

45. Patent examiners are grossly overworked. According to a report issued by the United States Government Accountability Office, patent examiners are expected to process an average of 87 patent applications per year and have time quotas set to allow for a total of 19 hours to process each application from its filing through its final acceptance or rejection. There is also a system in place to tie bonus compensation to the number of applications processed to completion which further compounds the time pressures on the patent examiners.

46. Solvay’s patent application for AndroGel was voluminous, and included submission to the patent examiner of multiple disclosure statements, which indentified more than 400 articles and patents that discussed previous testosterone and hormone therapies, along with copies of each of these hundreds of articles and patents in numerous notebooks, totaling more than three feet of materials.

47. Both the ‘777 Application and the ‘894 patent are directed to pharmaceutical compositions containing testosterone gel formulations, as well as methods of using these compositions to treat hypogonadism.

48. None of the originally filed claims in the ‘777 Application recited sodium hydroxide whose chemical symbol is “NaOH.”

49. As set forth below, (1) the specification of the ‘777 Application

provides no written description support for any range of concentrations of sodium hydroxide (either pure or in solution) and the sole mention of sodium hydroxide is a single concentration in a single formulation as shown in Table 5; and (2) when claims were later added reciting the ranges of sodium hydroxide - additions for which there was absolutely no written description in support - those ranges indisputably referred to ranges of amounts of pure (anhydrous) sodium hydroxide, rather than ranges of amounts of a dilute sodium hydroxide solution such as 0.1 N.

50. The only reference to sodium hydroxide in the entire specification is listed in Table 5 (shown below), which discloses a single formulation having a very specific amount (*i.e.* 4.72 grams) of a very specific sodium hydroxide solution (*i.e.* 0.1 N NaOH).

TABLE 5

Composition of AndroGel®

SUBSTANCE	AMOUNT (w/w) PER 100g OF GEL
Testosterone	1.0g
Carbopol 980	0.90g
Isopropyl myristate	0.50g
0.1 N NaOH	4.72g
Ethanol (95% w/w)	72.5g*

Purified water (qsf)	100.0g

*corresponding to 67g of ethanol

The '777 Application did not disclose the concept of a range of sodium hydroxide concentrations in the pharmaceutical formulation.

51. The phrase "0.1 N" indicates that the sodium hydroxide is in dilute aqueous solution (roughly 4 grams of sodium hydroxide per 1000 grams of solution), as opposed to the pure (anhydrous) form of sodium hydroxide. In 4.72 grams of a 0.1 N NaOH solution, there are approximately 0.019 grams of sodium hydroxide and approximately 4.70 grams of water. Therefore, the overall concentration of sodium hydroxide concentration in the AndroGel formulation described in Table 5 was roughly 0.019 percent (0.019 grams in a total of 100 grams of formulation).

52. On October 29, 2001, Solvay filed an Amendment with the PTO that cancelled certain originally-filed claims and added others. New dependent claims 45 and 64 recited sodium hydroxide, but in both of these new dependent claims, the term "sodium hydroxide" appears alone without any indication of either (a) a range (*e.g.*, "about 1% to about 5%) or (b) a modifier indicating that the recited amount reflected the weight of a dilute solution (*e.g.*, "0.1 N") rather than the weight of pure (anhydrous) sodium hydroxide. Additionally, the remarks in Solvay's submission did not mention either of these dependent claims or sodium

hydroxide.

53. Solvay filed a Supplemental Amendment on December 20, 2001 cancelling dependent claims 45 and 64 and adding new claims. Neither the new claims nor the applicants' remarks in the Supplemental Amendment pertained to sodium hydroxide.

54. Solvay filed a Second Supplemental Amendment on February 2, 2002. The Second Supplemental Amendment changed all independent claims (except for one) to recite weight ranges for pure (anhydrous) sodium hydroxide, *i.e.*, "about 1% to about 5% and "about 1% to about 3%." None of those proposed claims referred to the weight (*e.g.* 0.1 N). Solvay cited Table 5 and stated, "Note that 4.72g of 0.1 NaOH = 1.8g NaOH in 100g of gel, or about 1.8%." By making that statement- *i.e.*, by converting the 4.72 grams of a 0.1 N solution hydroxide in AndroGel to a measure of pure (anhydrous) sodium hydroxide - Solvay demonstrated its intent to express the sodium hydroxide limitation in the claims as pure sodium (anhydrous) hydroxide rather than as a 0.1 N solution. The remarks did not otherwise mention sodium hydroxide.

55. Although the 1.8g NaOH in 100g of gel is within the range of "about 1% to about 5%" and "about 1% to 3%" range recited in the newly added claims, there was no other calculation involving sodium hydroxide supplied by Solvay supporting this range.

56. The calculation converting the 4.72g of 0.1 NaOH to its equivalent amount in pure form in the AndroGel composition was erroroneous by a factor of roughly 100. That is, the equivalent amount of pure sodium hydroxide in the AndroGel composition in Table 5 is not 1.8 grams, but rather about 0.018 grams, per 100 grams of gel.

57. Solvay further amended the claims on two separate occasions subsequent to filing the Second Supplemental Amendment, but Solvay did not amend the claims to recite ranges for sodium hydroxide in a solution by inserting "0.1 N" or the like in either of them.

58. On January 7, 2003 the '894 patent issued. The five independent claims (*i.e.* claims 1, 9, 10 and 18) recite:

1. A pharmaceutical composition, consisting essentially of:

   a. about 0.5% to about 10% testosterone;
   b. about 30% to about 98% alcohol selected from the group consisting of ethanol and isopropanol;
   c. about 0.1% to about 5% isopropyl myristate;
   d. about 1% to about 5% sodium hydroxide; and
   e. about 0.1% to about 5% of a gelling agent, wherein the percentages of components are weight to weight of the composition.

9. A hydroalcoholic gel formulation, consisting essentially of:

   a. about 1% to about 2% testosterone;
   b. about 50% to about 75% ethanol;
   c. about 0.5% to about 2% isopropyl myristate
   d. about 1% to about 3% sodium hydroxide;

e. about 0.5% to about 2% polyacrylic acid; and
f. water in an amount sufficient to make the formulation 100%; wherein the percentages of components are weight to weight of the formulation.

10. A unit dose packet comprising inner and outer surfaces, and a pharmaceutical composition inside the packet, the composition consisting essentially of:

a. about 0.5% to about 5% testosterone;
b. about 30% to about 98% ethanol;
c. about 0.1% to about 5% isopropyl myristate;
d. about 1%to about 5% sodium hydroxide; and
e. about 0.1% to about 5% of a gelling agent;
wherein the percentages of components are weight to weight of the composition.

18. A method for administering an active agent to a human subject in need thereof, the method comprising:

a. providing a phannaceutical [sic] composition consisting essentially of:

(i) about 0.5% to about 5% testosterone;
(ii) about 0.1% to about 5% of a gelling agent;
(iii) about 0.1% to about 5% isopropyl myristate;
(iv) about 1% to about 5%sodium hydroxide; and
(v) about 30% about 98% alcohol selected from the group consisting of ethanol and isopropanol;
wherein the percentages are weight to weight of the composition; and

Thus, each of the claims 1, 9, 10 and 18 specify that the pure sodium hydroxide accounts for at least "about 1%" sodium hydroxide on a "weight to weight basis," but as set forth above, there was no basis for those claims.

59. Solvay was required to list the patent within 30 days of its issuance in order to invoke the 30-month stay pursuant to the Hatch-Waxman Act. On information and belief, Solvay submitted the '894 patent for listing in the Orange Book, within 30 days, along with a signed declaration made under oath pursuant to 21 C.F.R. 314.53 certifying that one or more of the issued claims of the '894 patent could reasonably be asserted against a person who engaged in the unauthorized manufacture, use, or sale of AndroGel.

60. On or about June 12, 2003, Solvay requested that the PTO "correct" many of the claims of the '894 patent. Solvay knew the '894 patent as it had been issued did not claim the generic AndroGel product that was subject of the Generic Defendants ANDAs because, *inter alia*, like the FDA-approved AndroGel product, Watson and Paddock's generic AndroGel products do not contain the concentration levels of pure sodium required by the relevant claims of the '894 patent as issued.

61. Solvay knew that the Generic Defendants did not plan to market the compositions claimed in the relevant claims of the '894 patent because the relevant '894 patent claims would be too harmful to be used on human skin and the Generic Defendants were seeking to market their products as an AB-rated equivalent of Solvay's AndroGel, which contained much lower levels of sodium hydroxide in a solution that would not be too caustic to human skin.

62. Solvay filed a Request for a Certificate of Correction ("COC") with the PTO to correct its patent. One of the things the Request sought was to add the phrase "0.1N" before the term "sodium hydroxide" in claims 1, 9 10, and 18 of the '894 patent. Solvay represented to the PTO that "the mistakes were made in good faith and that the proper language is contained throughout the specification, see for example, column 13, Table 5 ("0.1 N NaOH" (sodium hydroxide)). As such, the correction does not involve such changes in the patent that would constitute new matter of reexamination." *See* WA000707. However, Solvay failed to disclose to the PTO that (1) the reference to "0.1 N NaOH" appeared only once (rather than "throughout") the specification and (2) the change did introduce "new matter" because the specification nowhere disclosed any ranges for "0.1 N NaOH" as recited by the purportedly "corrected" claims.

63. The COC was issued on December 16, 2003. As "corrected," the five independent claims recite:

> 1. A pharmaceutical composition, consisting essentially of:
>
> a. about 0.5% to about 10% testosterone;
> b. about 30% to about 98% alcohol selected from the group consisting of ethanol and isopropanol;
> c. about 0.1% to about 5% isopropyl myristate;
> d. about 1% to about 5% 0.1 N sodium hydroxide; and
> e. about 0.1% to about 5% of a gelling agent,
>
> wherein the percentages of components are weight to weight of the composition.

9. A hydroalcoholic gel formulation, consisting essentially of:

g. about 1% to about 2% testosterone;
h. about 50% to about 75% ethanol;
i. about 0.5% to about 2% isopropyl myristate
j. about 1% to about 3% 0.1 N sodium hydroxide;
k. about 0.5% to about 2% polyacrylic acid; and
l. water in an amount sufficient to make the formulation 100%; wherein the percentages of components are weight to weight of the formulation.

10. A unit dose packet comprising inner and outer surfaces, and a pharmaceutical composition inside the packet, the composition consisting essentially of:

a. about 0.5% to about 5% testosterone;
b. about 30% to about 98% ethanol;
c. about 0.1% to about 5% isopropyl myristate;
d. about 1%to about 5% 0.1 N sodium hydroxide; and
e. about 0.1% to about 5% of a gelling agent;
wherein the percentages of components are weight to weight of the composition.

18. A method for administering an active agent to a human subject in need thereof, the method comprising:

a. providing a pharmaceutical [sic] composition consisting essentially of:

(vi) about 0.5% to about 5% testosterone;
(vii) about 0.1% to about 5% of a gelling agent;
(viii) about 0.1% to about 5% isopropyl myristate;
(ix) about 1% to about 5% 0.1 N sodium hydroxide; and
(x) about 30% about 98% alcohol selected from the group consisting of ethanol and isopropanol; wherein the percentages are weight to weight of the composition; and

b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject so as to achieve a serum concentration within a range between about 300 ng testosterone per dl serum to about 1050 ng testosterone per dl serum within at least about 36 hours of daily dosing of the composition.

31. A method for administering an active agent to a human subject in need thereof, the method comprising:

a. providing a pharmaceutical composition consisting essentially of:
(i) about 0.5% to about 5% testosterone;
(ii) about 0.1% to about 5% isopropyl myristrate;
(iii) about 30% to about 98% of an alcohol selected from the group consisting of ethanol and isopropanol; and
(iv) about 0.1% to about 5% of a gelling agent;
wherein the percentages are weight to weight of the composition; and

b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject wherein serum concentration is substantially maintained between about 400 ng testosterone per dl serum to about 1050 ng testosterone per dl serum for at least 24 hours after the subject has applied the daily dose of the composition for at least 2 consecutive days.

64. However, a COC only applies to causes of action that arise after the issuance of the COC. This reflects the policy that after the patent is issued, it serves as a public notice. Therefore, patentees have a duty to prepare their patent applications with care and to scrutinize their patents when issued for accuracy and

correctness to determine whether it contains any errors requiring a COC.

65. Pursuant to 35 U.S.C. § 271 (e)(2)(A), the filing of an ANDA constitutes an act of infringement. Accordingly, in this matter, the infringement claims that arose by Watson and Paddock filing their ANDAs and providing notice thereof arose in May 2003, **prior** to the issuance of the COC. Therefore, by statute, the COC was inapplicable in the patent litigation as a matter of law. Solvay could not properly claim the "corrected" patent in that litigation and because the claims in the patent as issued did not cover AndroGel or AB generic versions of AndroGel, no reasonable litigant could have believed that Watson's and Paddock's generic versions of AndroGel infringed the '894 patent.

66. Additionally, even if the "corrected" claims by the COC were applicable in the Solvay patent infringement lawsuits, no reasonable litigant could have believed that the "corrected" claims were valid.

Solvay Improperly Sues Generic Defendants For Infringement Of The '894 Patent

67. In early 2003, Watson filed ANDA No. 76-737 for approval of Watson's AB-rated generic equivalent to AndroGel. Watson's ANDA contained a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by its ANDA. On July 8, 2003, Watson provided Solvay with the requisite notice that it filed an ANDA containing a Paragraph IV certification that

the '894 patent was invalid, unenforceable, and/or not infringed by Watson's ANDA.

68. In August 2003, Solvay sued Watson for infringement of the '894 patent.

69. In early 2003, Paddock filed with the FDA ANDA No. 76-744 for approval of Paddock's AB-rated generic equivalent to AndroGel. Paddock's ANDA contained a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by its ANDA. On July 8, 2003, Paddock provided Solvay with the requisite notice that it filed an ANDA containing a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by Paddock's ANDA.

70. In or about July 2003, Defendants Paddock and Par entered into an agreement whereby Par would market the generic version of AndroGel in the United States that Paddock manufactured. This agreement also provided that Par share litigation costs with Paddock, market in the U.S. the generic version of AndroGel and share in the profits. Par entered into this agreement after conducting due diligence on Paddock's ANDA in light of Solvay's formulation patent.

71. In August 2003, Solvay sued Paddock for infringement of the '894 patent.

72. Under the Hatch-Waxman Act, the filing of Solvay's patent

infringement lawsuits triggered automatic stays of FDA final approval of the generic versions of AndroGel for thirty months until January 2006. Prior to the initiation of the patent infringement lawsuits, neither Solvay nor Besins requested or sought to obtain any sample of the Generic Defendants' proposed drug products, any portion of the Generic Defendants' ANDAs or any other information from the Generic Defendants related to their proposed generic products.

73. On information and belief, prior to filing their complaint, Solvay and Besins' sole information regarding the Generic Defendants' ANDA products came from the notice letters explaining why neither of the ANDAs nor the generic products infringed on the '894 patent.

74. On October 27, 2004 Paddock's ANDA was tentatively approved. Paddock's ANDA received its final approval from the FDA on May 27, 2007.

75. In late January 2006, Watson received final approval from the FDA to market its AB-rated generic version of AndroGel, meaning the FDA determined that Watson's generic AndroGel was as safe and effective as branded AndroGel. Watson was therefore granted 180 days of marketing exclusivity for being the first to file an ANDA containing a Paragraph IV certification.

Solvay And Besins Put Their Scheme In Motion

76. Solvay and Besins were well aware that testosterone, the active substance in AndroGel, was known and unpatentable. They were also aware that,

under the Hatch-Waxman Act, their new dosage form exclusivity was set to expire on February 28, 2003 and that ANDAs seeking to market generic versions would be soon to follow. Solvay and Besins developed a scheme to delay generic competition. As part of the scheme, they would list a patent in the Orange Book under NDA no. 21-015 for AndroGel, and delay would be generic competition for up to 30 months by filing "sham" patent litigation.

77. A critical component of Solvay's scheme was timing. Solvay knew that generic companies only need to file a Paragraph IV Certification with respect to patents that are listed in the Orange Book. Unless there was a patent listed in the Orange Book, Solvay and Besins would not have been able to force the Generic Defendants to file Paragraph IV Certifications triggering a 30-month FDA stay by filing suit.

78. Solvay, in its haste to get the patent listed in the Orange Book, made numerous mistakes. Many of the claims in the '894 patent were clearly invalid and could not reasonably be asserted against the Generic Defendants. Solvay then compounded the problem by affirmatively misrepresenting facts regarding the '894 patent to the PTO.

79. Solvay could not have reasonably believed that the '894 patent was proper for listing at the time it submitted the '894 patent. The FDA regulations in effect at the time provided that "[f]or patents that claim a drug substance or drug

product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application, or that claim a drug substance that is a component of such a product. For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application." 21 C.F.R. 314.53. The then-existing claims of the '894 patent did not support listing because the '894 patent did not claim AndroGel (or testosterone drug substance that is a component of AndroGel) or an approved method of use for AndroGel.

80. It is well established law that "[o]ne who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that [independent] claim." *Wahpeton Co., Inc. v. Frontier, Inc*., 870 F.2d 1546, 1552 (Fed. Cir. 1989). Therefore, unless AndroGel (or an approved method of using AndroGel) fell within the scope of the five originally issued independent claims (*i.e.*, claims 1, 9, 10, 18 and 31) of the '894 patent, it could not fall within the scope of any of the remaining originally-issued claims of the '894 patent.

81. As shown above, each of the originally-issued claims, 1, 9, 10 and 18, required a formulation having at least "about 1%" sodium hydroxide. Tellingly, Solvay's pleadings from the patent litigation against the Generic Defendants, admit

that the phrase "sodium hydroxide" means the pure (anhydrous) form of sodium hydroxide. It also admitted that the amount of sodium hydroxide recited in the independent claims is 50 to 250 times greater than the amount of sodium hydroxide in AndroGel marketed under NDA No. 21-105. Therefore, no reasonable litigant could assert that originally-issued claims 1, 9, 10 or 18 (or the claims depending therefrom) covered either AndroGel (or the testosterone drug substance that is a component of AndroGel) or any generic version of AndroGel or an approved method of use for AndroGel or any generic version of AndroGel. Solvay also admitted that a skilled pharmaceutical chemist would determine that the amount of pure sodium hydroxide (anhydrous) stated in the originally-issued claims 1, 9, 10 and 18 is far too caustic to be used and would cause damage to human skin. Neither independent claims 1, 9, 10 and 18, nor the claims depending from those claims, could justify the inclusion of the '894 patent in the Orange Book.

82. Likewise, the remaining independent claim, claim 31, could also not be construed to cover a method for using AndroGel product or a generic version of AndroGel. Claim 31 states a "pharmaceutical composition consisting essentially of: (i) about 0.5% to about 5% testosterone; (ii) about 0.1% to about 5% isopropyl myrisate; (iii) about 30% to about 98% of an alcohol selected from the group consisting of ethanol and isopropanol; and (iv) about 0.1% to about 5% of a gelling agent…" The terms "consisting essentially of" indicate that a claim "necessarily

includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." *PPG Indus. V. Guardian Indus. Corp*., 156 F.3d 1351, 1354 (Fed. Cir. 1998). Therefore, for a particular pharmaceutical formulation to meet the limitations of claim 31, it (1) must include testosterone, isopropyl myristate, a gelling agent, and either ethanol or isopropanol in the required amounts and (2) must exclude any additional ingredient that materially affects the basic and novel properties of the invention. In its briefing during the patent infringement litigation, Solvay has admitted that the basic and novel properties of its "invention" are the ability to produce sufficient plasma levels of testosterone to treat hypogonadism in patients. Sodium hydroxide materially affects the basic and novel properties of the "invention" because the Carbopol gelling agent in the AndroGel formulation requires sodium hydroxide to function properly. No reasonable litigant could believe that claim 31 encompassed a method of using AndroGel. Therefore, neither claim 31 nor any of its dependent claims could have provided Solvay with justification to submit the '894 patent in the Orange Book.

83. For the same reasons discussed above concerning Solvay's improper listing of the '894 patent, Solvay could not have reasonably believed that the Generic Defendants' ANDAs would infringe on the '894 patent when it filed the patent infringement case against Generic Defendants. On information and belief,

generic AndroGel did not have "about 1%" sodium hydroxide as required by originally-issued independent claims 1, 9, 10 and 18 (and their dependent claims). Solvay admitted that the amount of pure sodium hydroxide (anhydrous) in originally-issued claims 1, 9, 10 and 18 would be too caustic to be used the claimed formulation and would damage the skin. The Generic Defendants' ANDAs could not contain and Solvay could not have believed that Generic Defendants' ANDAs contained the amount of sodium hydroxide recited in Solvay's claims. Therefore, no reasonable litigant could assert that originally-issued claims 1, 9, 10, or 18 were infringed and no reasonable litigant could expect to prevail. Solvay's sole purpose in initiating the patent infringement lawsuits was to seek the automatic stay and, therefore the litigation was baseless and a "sham."

84. Any claim by Solvay that the COC cured the defects is disingenuous. Solvay's COC did not issue for several months after Solvay filed the patent infringement suits, and the law is well settled that a certificate of correction is "not effective" for "causes arising before its issuance." *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280. 1294 (Fed. Cir. 2000). Solvay could not have reasonably believed that the COC was effective before it was issued. Additionally, the cause of action for patent infringement arises upon the filing of the ANDA under 35 U.S.C. § 271(e)(2)(A) and cannot reasonably be viewed as a continuing tort.

85. Neither Solvay, Besins, or any reasonable litigant could not have believed that claims 1-30 were valid either in their originally-issued form or their "corrected" form. Both sets of claims failed to comply with the written description requirement. The "corrected" set was also invalid because Solvay misrepresented facts to obtain it.

86. "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not…" *Amgen Inc. v. Hoechst Marion Roussel, Inc*., 314 F.3d 1313, 1330 (Fed. Cir. 2003). In order to satisfy the written description requirement, the disclosure of the specification must "convey with reasonable clarity to those skilled in the art, that, as of the filing date sought, [the inventor] was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Claims 1-30, both in their original and "corrected" forms recite a range of sodium hydroxide weight-to-weight percentages. The '777 Application, as originally filed, teaches no range of sodium hydroxide for a pharmaceutical composition. The sole reference to sodium hydroxide is a single weight-to-weight percentage in a single example in Table 5. Nothing in the '777 Application could reasonably be viewed as conveying "with reasonable clarity to those skilled in the art" that as of the filing of the '777 Application, the inventors were in possession of the ranges of sodium hydroxide claimed in either the originally or "corrected" claims.

87. 35 U.S.C. § 255 permits the Patent Office to correct either mistakes of "minor character" or mistakes of a "clerical or typographical nature." A mistake that, if corrected, would broaden the scope cannot be a "minor character." A broadening correction can only be made when it is "manifest" or "immediately apparent" and where it is "clearly evident" for the intrinsic evidence the one appropriate way to correct the error. Solvay did not and could not satisfy these requirements.

88. Solvay misrepresented to the PTO the existence of written description support in the '777 Application. Solvay represented that "the mistakes were made in good faith and that the proper language is contained throughout the specification, see, for example, column 13, Table 5 ("0.1 N NaOH" (sodium hydroxide)). As such, the correction does not involve such changes in the patent that would constitute new matter or that would require reexamination." See WA000707. These were deliberate misrepresentations made to the PTO. The reference to "0.1 N NaOH" was not made "throughout," but only once and Solvay's requested change did introduce "new matter" because the specification did not disclose any ranges for "0.1 N NaOH" as recited by the "corrected" claims.

89. Both Watson and Paddock filed counterclaims in the patent litigation seeking declaratory judgment that their products did not infringe and/or the '894 patent was invalid.

90. The Generic Defendants also moved for summary judgment of invalidity as to certain claims of the '894 patent. Had the case not settled, the Generic Defendants would have also moved for summary judgment of non-infringement following the claim construction ruling by the court.

91. Upon information and belief, the briefing on the summary judgment between Solvay and Watson relating to invalidity was completed on January 19, 2006, and therefore had been pending for about 9 months prior to the patent litigation settlement. Upon information and belief, the only remaining briefing on the invalidity motions between Solvay and Paddock at the time of the settlement was Paddock's reply brief.

92. Therefore, as a result of the actions, facts and circumstances alleged above, each of the Defendants knew (or should have known) that, Solvay's patent claims were baseless and that absent the settlements, Solvay would have lost the patent litigation on the merits.

93. As alleged above, in January 2006, Watson received final FDA approval for its generic version of AndroGel which meant that the FDA determined that Watson's generic was as safe and effective as branded AndroGel. This approval would allow Watson to launch its generic version of Androgel unless Solvay could obtain a preliminary injunction in the patent infringement case to stop the launch.

94. Solvay did not file for a preliminary injunction to prevent Watson from launching a generic version of Androgel, but rather opted to formulate anticompetitive agreements to settle the patent disputes and eliminate the threat of competition by a generic.

Solvay's Settlement With Watson

95. In order to analyze its settlement options, Solvay put together a financial model known as "Project Tulip." The purpose of this model was to assess whether the Generic Defendants would accept a delayed entry date by evaluating the Generic Defendants' expected return if they continued to litigate. Solvay concluded that Watson and Par might agree to a settlement to defer generic entry, but that Solvay would have to pay Watson and Par.

96. The Project Tulip analysis also demonstrated to Solvay that if it delayed competition until 2015 by payments made to the Generic Defendants it would still make more in AndroGel profits than by continuing to litigate.

97. At the beginning of the settlement negotiations, Watson proposed an arrangement in which Watson would co-promote AndroGel to doctors and share AndroGel revenues. Solvay had hired a consulting firm just a few months before to assist Solvay to construct a comprehensive analysis of Solvay's AndroGel promotion options. The analysis concluded that AndroGel co-promotion was not likely for Solvay, and in any event, Watson did not meet the set criteria for

potential co-promotion partners. Despite this, because of Solvay's desire to protect its AndroGel's revenues for another nine years until 2015, it quickly reconsidered allocating a portion of AndroGel's revenues to Watson.

98. Solvay's payment to Watson had to be substantial enough to compensate Watson for potential risk posed by Solvay's planned new version of AndroGel, which threatened to destroy the market for AndroGel and make Watson's generic AndroGel less valuable. Branded drug companies commonly employ the use of a "line extension," or a new branded product that is similar to the existing branded product to preserve sales of a branded drug in the face of imminent generic competition. The brand company encourages switching from the old version to the new line extended version.

99. During settlement negotiations Solvay informed Watson of its plan to develop and market a testosterone gel containing 1.62% testosterone, more than 1% testosterone contained in AndroGel, which would allow patients to experience similar therapeutic results with less volume of gel. Solvay intends to switch to the new lower volume product before 2015, in part because generic versions of the new AndroGel would not automatically substitute for Solvay's new branded drug.

100. On September 13, 2006, Solvay and Watson entered into written agreements to settle their patent litigation. Watson agreed to refrain from marketing AndroGel until August 31, 2015, or earlier if another generic company

launched a generic version of AndroGel prior to that date. Watson had a 180-day exclusivity period which meant that by delaying its own launch, Watson could also delay the later generics from entering the market.

101. Solvay and Watson simultaneously entered into a co-promotional deal wherein it was projected that Solvay would pay Watson approximately $19 million during the first year of the agreement and up to $30 million annually by the end of the agreement.

102. The compensation Solvay agreed to pay to Watson was designed to and did induce Watson to settle the AndroGel patent litigation. Even though Watson, in the patent litigation, had alleged and claimed in its affirmative defenses and answer that the patent litigation was baseless, nevertheless it conspired with Solvay, by agreeing to settle "sham" litigation, take the money and share in Solvay's monopoly's profits.

103. Solvay and Watson filed a voluntary stipulation of dismissal ending their patent litigation in the district court. The parties did not file their settlement and co-promotion agreements with the court, nor were the agreements contingent upon court approval.

Solvay's Settlement With Par And Paddock

104. Under its partnership with Paddock, Par was responsible for conducting the patent litigation with Solvay and negotiating any settlement.

105. Par also was only interested in delaying its entry to 2016 if it received compensation for the delay.

106. In order to help them agree on a value of the settlement, Par and Solvay exchanged forecasts analyzing the profits Par would make from sales of generic AndroGel beginning in 2007.

107. Solvay and Par agreed upon an amount in which Par would receive for settling the litigation, and incredibly, made this agreement prior to agreeing to what Par would have to do in exchange for the payments other than to defer generic entry until 2015.

108. On May 13, 2006, the parties confirmed via e-mail their "agreed-upon settlement of $12 million per year for 6 years coupled with manufacturing/development and/or co-promotion between Par and Solvay."

109. After the parties' agreement on the amount Solvay would pay Par, the parties met to discuss the business arrangement that would accompany the settlement and the allocation of the money between Paddock and Par. The parties agreed that Par would co-promote AndroGel to doctors and receive $10 million per year, and Paddock would serve as a back-up manufacturer for AndroGel and receive $2 million per year.

110. On September 13, 2006, the same day that Solvay and Watson executed their agreement, Solvay, Besins, Par and Paddock entered into written

agreements to settle their patent litigation. Pursuant to the agreement, Par and Paddock agreed to refrain from marketing generic AndroGel until February 28, 2016, or earlier if another generic company launched a generic version of AndroGel prior to that date.

111. Simultaneously to signing its agreements with Solvay, Par agreed to transfer $6 million upfront to Paddock through a transfer of title of Paddocks' ANDA to Par. This payment was a condition to gaining Paddock's agreement to the patent settlement.

112. The money Solvay agreed to pay Paddock and Par was designed to, and did, induce Paddock and Par to settle the AndroGel patent litigation by agreeing to refrain from marketing generic AndroGel until 2016. Rather than competing, Paddock and Par agreed to conspire with Solvay to settle "sham" litigation, take the money and share in Solvay's monopoly's profits.

113. Solvay's own financial analysis demonstrated that Solvay knew it would be better off sharing its monopoly profits so that the Generic Defendants would agree to stay out of the market until 2015.

114. The district court hearing the patent litigation dismissed Solvay's infringement suit against Paddock under a consent judgment filed by the parties. The parties did not file their settlement and co-promotion and back-up agreements with the court, nor were the agreements contingent upon court approval.

Solvay's Patent Was Unlikely To Prevent Generic Competition

115. Prior to the execution of the settlement agreements not to market their respective generic versions of AndroGel, Watson and Par/Paddock strongly took the position that the '894 patent was invalid. They did so in various motions submitted to the patent court pursuant to Federal Rules of Civil Procedure 11 as well as perjury statutes alleging that:

(1) The patent was invalid under 35 U.S.C. § 102(b) for prior commercial sale or public use of the patented invention, in that Besins offered the invention for sale to Solvay in 1995, a fact that Besins withheld from the PTO.

(2) The patent was invalid as obvious under 35 U.S.C. § 103 because the gel formulations and related methods covered by the patent were obvious variations of existing products and methods. As a Paddock executive noted in a 2006 e-mail characterizing the views of Paddock's CEO, Paddock was "providing [testosterone] gel formulations to customers over 10 years ago, so the patent simply cannot be valid."

(3) Many of the patent claims were invalid under 35 U.S.C. § 112 for failure to meet the "written description" requirement.

116. Watson made the additional argument that the patent was

unenforceable because Solvay and Besins did not disclose their commercial supply agreement to the patent examiner at the time they applied for the '894 patent. The Generic Defendants also vigorously argued that the COC, which changed the scope of the patent claims, was invalid and/or did not apply to the patent infringement litigation because it had been issued after the litigation began.

117. Most notable, Watson and Par/Paddock also argued that their generic formulations did not infringe on the '894 patent because their formulations fell outside the limited scope of the patent claims, their products contained different ingredients, and ingredients in different amounts than those specified in the '894 patent.

118. During the patent litigation, the Generic Defendants developed significant evidence to buttress their arguments that their products did not infringe the '894 patent.

119. These arguments are important because: (1) the arguments developed by Watson, and Par/Paddock would have been used to prevent Solvay from obtaining a court order preventing the Generic Defendants from competing with Solvay; and (2) although there is a rebuttable presumption that a patent is valid, there is no such presumption of infringement.

120. As set forth above, by the time of the settlements, Watson and Par/Paddock had filed motions for summary judgment on issues of invalidity and

unenforceability, and alleged additional matters in their claim construction briefing and expert reports.

121. In recognizing the weakness in their patent claims, Solvay and Besins decided to pay millions of dollars to the Generic Defendants rather than seeking injunctive relief from the Court.

But For The Improper Patent Listing And "Sham" Litigation, Generic AndroGel Products Would Have Entered The Market

122. Shortly after the expiration of the 30-month stay, on January 27, 2006, Watson received final FDA approval to market its generic AndroGel. But for the improper listing and "sham" litigation, Watson would have and could have begun marketing its generic AndroGel on that date.

123. On October 27, 2004, Par/Paddock received tentative approval to market their generic AndroGel. Par/Paddock received final FDA approval to market their generic AndroGel on May 27, 2007. But for the improper listing of the '894 patent and the "sham" litigation, Par and Paddock would have and could have begun marketing their generic AndroGel on May 27, 2007.

124. Defendants are well aware that any delay in generic entry leads directly to damages to Plaintiff and the Class it seeks to represent as well as continuing inflated profits because it allows them to continue to enjoy the benefits of an absence of competition for AndroGel. In the meantime, any such delay

causes substantial harm to Plaintiff and indirect purchasers of AndroGel.

125. If a generic version of AndroGel had been introduced to the market when the FDA approvals were received, Plaintiff and members of the Class would have substituted the lower-priced generic AndroGel for all or a portion of their purchases of branded AndroGel, or would have paid substantially less for branded AndroGel because Solvay would have lowered net AndroGel prices in response to competition, or would have reduced the rate of price increases for AndroGel in response to such competition.

126. As a consequence of Defendants' initiation and settlement of "sham" litigation, Plaintiff and members of the Class have been deprived of the benefits of free and open competition in their purchases. Purchasers of AndroGel were required to continue purchasing brand name AndroGel when a less expensive generic product would have otherwise been available.

CLASS ACTION ALLEGATIONS

127. Plaintiff brings this action pursuant to Rule 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of itself and the following Class (the "Class"):

> All persons and entities throughout the State of California who purchased AndroGel for consumption by themselves, their families, or which paid for or were reimbursed in whole or in part for their members, employees, insureds, participants, or beneficiaries (the "Class") during the period from at least

> January 2006, through the date on which the anticompetitive effects of Defendants' conduct cease ("Class Period"). Excluded from the Class are all Defendants, their officers, subsidiaries and all affiliates; all government entities (except for governmental-funded employee benefit plans); and all persons or entities that purchased AndroGel for purposes of resale, or directly from any of the Defendants or affiliates.

128. The Class is so numerous that joinder of all members is impracticable. Class members include consumers and third party payors. Upon information and belief, the Class includes at least hundreds of members.

129. There are questions of law and fact common to the Class, including but not limited to, the following:

a. whether Defendants combined, agreed, or conspired as alleged herein in restraint of trade and/ or engaged in sham litigation;

b. whether Defendants' agreement, combination, or conspiracy was unlawful;

c. whether Defendants' unlawful conduct as alleged herein has affected interstate commerce;

d. whether Defendants' unlawful conduct caused Plaintiff and the other members of the Class to pay more for AndroGel and its generic equivalents than they would have paid absent Defendants' conduct; and

e. whether Defendants' unlawful conduct caused antitrust injury to the business or property of Plaintiff and the members of the Class and, if so, the appropriate relief and/or measure of damages.

130. These and other questions of law or fact are common to the members of the Class and predominate over any questions affecting individual members because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' collusive conduct.

131. Plaintiff's claims are typical of the claims of the Class because Plaintiff and all members of the Class suffered antitrust injury by the same wrongful conduct by the Defendants. All members of the Class have all paid artificially inflated prices for AndroGel and its generic equivalents resulting from Defendants' Agreement to exclude generic competition.

132. Plaintiff will fairly and adequately represent and protect the interests of the Class. Plaintiff has retained counsel experienced in class action and antitrust litigation. Plaintiff has no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

133. A class action is superior to any other available methods for the fair and efficient adjudication of this controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single

forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would require. The benefits of proceeding by way of class action, including providing injured persons or entities with a method for obtaining redress on claims that they might not be able to pursue individually, substantially outweigh any difficulties that may arise in the management of a class action.

134. Plaintiff does not know of any difficulty that would be encountered in the management of the claims advanced by the Class that would preclude certification.

INTERSTATE TRADE AND COMMERCE

135. During the Class Period, AndroGel was sold throughout the United States. AndroGel was manufactured and sold in a continuous and uninterrupted flow of commerce across state lines. Defendants' unlawful activities alleged in this Amended Complaint have occurred in and have had a substantial effect upon interstate commerce.

136. In furtherance of their unlawful conduct, Defendants employed the United States mail and interstate and international telephone lines, as well as means of interstate and international travel.

ANTICOMPETITIVE EFFECTS

137. Defendants have undertaken the foregoing unlawful courses of

conduct for the following purposes and with the following effects:

a. prices for AndroGel and its generic equivalents have been fixed, raised, maintained, or stabilized at artificially high and non-competitive levels;

b. buyers of AndroGel have been unable to purchase lower-priced generic versions of Androgel;

c. buyers of AndroGel and its generic equivalents have been deprived of the benefits of free and open competition in their purchases; and

d. competition in the production and sale of AndroGel and its generic equivalents has been restrained, suppressed, and eliminated.

DAMAGES

138. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of AndroGel. As a result of Defendants' illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, artificially inflated prices for AndroGel. Those prices were and are substantially greater than the prices they would have paid absent the illegal agreement, combination, conspiracy, sham litigation and other unlawful conduct alleged herein, because they were deprived of the opportunity to: (1) pay lower prices for

the generic versions of the drug; (2) pay lower prices for their AndroGel requirements by switching more of the volume of their purchases from the brand to the generic versions; and (3) pay lower prices for the brand name drug AndroGel. Plaintiff and members of the Class have sustained substantial losses and damage to their businesses and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

COUNT I

(FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR VIOLATIONS OF SECTION 1 OF THE SHERMAN ACT)

139. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

140. By entering into the scheme to prevent generic competition, and then entering into the Agreements to settle "sham" litigation, the purpose and effect of which was to restrain trade by keeping generic competition to AndroGel out of the market, Defendants and their co-conspirators have engaged in a continuing agreement, contract, understanding and conspiracy in restraint of trade to artificially raise, fix, maintain and/or stabilize prices for AndroGel, violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

141. Defendants' agreement, contract, understanding, combination, and/or

conspiracy has included concerted actions and undertakings among Defendants with the purpose and effect of fixing, raising, maintaining, or stabilizing the price of AndroGel and its generic equivalents.

142. For the purpose of formulating and effectuating their agreement, contract, understanding, combination, and/or conspiracy, Defendants and their co-conspirators performed, among others, the acts, practices and courses of conduct set forth above, and following acts:

a. initiating and participating in settling sham litigation regarding the validity of the AndroGel patent;

b. entering into illegal agreements to settle "sham" litigation by which the Generic Defendants agreed not to sell generic AndroGel in U.S. commerce in exchange for the promise of monetary payment by Solvay;

c. depriving indirect purchasers of the ability to purchase AndroGel and its generic equivalents at a competitive price; and

d. fixing, raising, maintaining and stabilizing the price of AndroGel.

143. The acts done by each of the Defendants as part of, and in furtherance of, their contract, combination, and/or conspiracy were authorized, ordered, or

done by their officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

144. Defendants' illegal contract, combination, and/or conspiracy to prevent the introduction into the U.S. marketplace of a generic version of AndroGel resulted in Plaintiff and members of the Class paying more than they would have paid for AndroGel and its generic equivalents absent Defendants' illegal conduct.

145. The purpose and effect of Defendants' conduct was to unreasonably restrain competition in the sale of AndroGel and its generic equivalents. To the extent required by law, the relevant product market is AndroGel and its AB-rated generic equivalents, and the relevant geographical market is the State of California.

146. Plaintiff and the Class are entitled to a declaratory judgment and injunction against Defendants preventing and restraining the violations set forth herein.

COUNT II

FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

147. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

148. By engaging in willful and exclusionary acts as part of a scheme to

maintain and extend monopoly power over AndroGel, Defendants have violated Section 2 of the Sherman Act, U.S.C. § 2.

149. By instituting litigation against Generic Defendants based on the blatantly unenforceable and invalid '894 patent, and settling the patent infringement litigation, Defendants engaged in sham litigation, which constitutes a willful and exclusionary act as part of a scheme to maintain and extend their monopoly power over AndroGel.

150. Defendants' actions to prevent the introduction into the U.S. marketplace of a generic version of AndroGel resulted in Plaintiff and members of the Class paying more than they would have paid for AndroGel and its generic equivalents absent Defendants' conduct.

151. To the extent required by law, the relevant product market is AndroGel and its AB-rated generic equivalents. There are no reasonable economic substitutes for AndroGel other than the AB-rated generic equivalents. Accordingly, Defendants have been able to profitably maintain the price of AndroGel well above competitive levels.

152. The relevant geographic market is the State of California.

153. Plaintiff and the Class are entitled to a declaratory judgment and injunction against Defendants preventing and restraining the violations set forth herein.

COUNT III

(Violation of the California Cartwright Act)

154. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

155. Defendants' contract, combination, trust or conspiracy was centered in, carried out, effectuated and perfected mainly within the State of California, and Defendants' conduct within California injured all members of the Class throughout California.

156. Beginning at a time presently unknown to Plaintiff, but at least as early as September 13, 2006, and continuing at least up to and including the present, Defendants and their co-conspirators entered into and engaged in a continuing unlawful trust in restraint of the trade and commerce described above in violation of Section 16720, California Business and Professional Code. Defendants, and each of them, have acted in violation of Section 16720 to fix, raise, stabilize and maintain prices of, and allocate markets for, AndroGel at supra-competitive levels.

157. The aforesaid violations of Section 16720, California Business and Professions Code, consisted, without limitation, of a continuing unlawful trust and concert of action among the Defendants and their co-conspirators, the substantial

terms of which were to fix, raise, maintain and stabilize the prices of AndroGel.

158. For the purpose of forming and effectuating the unlawful trust, the Defendants and their co-conspirators have done those things which they combined and conspired to do, including but in no way limited to the acts, practices and course of conduct set forth above and the following:

a. initiating and participating in settling sham litigation regarding the validity of the AndroGel patent;

b. entering into illegal agreements to settle "sham" litigation by which the Generic Defendants agreed not to sell generic AndroGel in U.S. commerce in exchange for the promise of monetary payment by Solvay;

c. depriving indirect purchasers of the ability to purchase AndroGel and its generic equivalents at a competitive price; and

d. fixing, raising, maintaining and stabilizing the price of AndroGel; and

159. The combination and conspiracy alleged herein has had, inter alia, the following effects:

a. price competition in the sale of AndroGel has been restrained, suppressed and/or eliminated in the State of California;

b. prices for AndroGel sold by Defendants and their co-conspirators have been fixed, raised, maintained and stabilized at artificially high, non-competitive levels in the State of California;

c. those who purchased AndroGel from Defendants and their co-conspirators have been deprived of the benefit of less expensive generic versions of AndroGel; and

d. Plaintiffs and the other members of the Class paid supra-competitive, artificially inflated prices for AndroGel.

160. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff and the members of the Class have been injured in their business and property in that they paid more for AndroGel than they otherwise would have paid in the absence of Defendants' unlawful conduct. As a result of Defendants' violation of Section 16720 of the California Business and Professions Code, Plaintiff seeks treble damages and the costs of suit, including reasonable attorneys' fees, pursuant to Section 16750(a) of the California Business and Professions Code.

COUNT IV
(Violation of the California Unfair Competition Law)

161. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

162. Defendants' business acts and practices were centered in, carried out, effectuated and perfected mainly within the State of California, and Defendants' conduct within California injured all members of the Class throughout California. Beginning on a date unknown to Plaintiff, but at least as early as September 13, 2006, and continuing thereafter at least up to the present, Defendants committed and continue to commit acts of unfair competition, as defined by Sections 17200, *et seq.* of the California Business and Professions Code, by engaging in the acts and practices specified above.

163. This Claim is instituted pursuant to Sections 17203 and 17204 of the California Business and Professions Code, to obtain restitution from these Defendants for acts, as alleged herein, that violated Section 17200 of the California Business and Professions Code, commonly known as the Unfair Competition Law.

164. The Defendants' conduct as alleged herein violated Section 17200. The acts, omissions, misrepresentations, practices and non-disclosures of Defendants, as alleged herein, constituted a common continuous and continuing course of conduct of unfair competition by means of unfair, unlawful and/or fraudulent business acts or practices within the meaning of California Business and Professions Code, Section 17200, *et seq.*, including, but not limited to, the following:

a. The violations of Section 1 of the Sherman Act, as set forth

above;

b. The violations of Section 16720, *et seq.*, of the California Business and Professions Code, set above;

c. Defendants' acts, omissions, misrepresentations, practices and non-disclosures, as described above, whether or not in violation of Section 16720, *et seq.* of the California Business and Professions Code, and whether or not concerted or independent acts, are otherwise unfair, unconscionable, unlawful or fraudulent;

d. Defendants' act and practices are unfair to consumers of AndroGel in the State of California, within the meaning of Section 17200, California Business and Professions Code; and

e. Defendants' acts and practices are fraudulent or deceptive within the meaning of Section 17200 of the California Business and Professions Code.

165. Plaintiffs and each of the Class members are entitled to full restitution and/or disgorgement of all revenues, earnings, profits, compensation and benefits which may have been obtained by Defendants as a result of such business acts or practices.

166. The illegal conduct alleged herein is continuing and there is no

indication that Defendants will not continue such activity into the future.

167. The unlawful and unfair business practices of Defendants, and each of them, as described above, have caused and continue to cause Plaintiff and the members of the Class to pay supra-competitive and artificially-inflated prices for AndroGel. Plaintiff and the members of the class suffered injury in fact and lost money or property as a result of such unfair competition.

168. The conduct of Defendants as alleged in this Complaint violates Section 17200 of the California Business and Professions Code.

169. As alleged in this Complaint, Defendants and their co-conspirators have been unjustly enriched as a result of their wrongful conduct and by Defendants' unfair competition. Plaintiff and the members of the Class are accordingly entitled to equitable relief including restitution and/or disgorgement of all revenues, earnings, profits, compensation and benefits which may have been obtained by Defendants as a result of such business practices, pursuant to the California Business and Professions Code, Sections 17203 and 17204.

COUNT V

(FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS)

170. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

171. As a result of their unlawful conduct described above, Defendants have been and will continue to be unjustly enriched. Defendants' unlawful acts impose barriers to entry for generic manufacturers seeking to compete in the relevant market. Defendants have been unjustly enriched, to the detriment of Plaintiff and the Class by the receipt of, at a minimum, unlawfully inflated prices and illegal profits on their sale of AndroGel products. Defendants have benefitted from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of their ill-gotten gains resulting from the overpayments for AndroGel products made by Plaintiff and the Class.

172. Plaintiff and members of the Class are entitled to the amount of Defendants' ill-gotten gains resulting from Defendants' unlawful, unjust and inequitable conduct. Plaintiff and the Class are entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiff and the Class members may make claims on a pro rata basis.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and members of the Class, respectfully requests:

1. An order certifying this action as a class action and appointing Plaintiff as representative of the Class and its counsel as Class Counsel;

2. A judgment declaring Defendants' contract, combination, or conspiracy and monopolization and conspiracy to monopolization as alleged herein to be an unlawful restraint of trade in violation of Sections 1 and 2 of the Sherman Act, in violation of the antitrust and consumer protection statutes set forth above, and common law of unjust enrichment;

3. That Defendants, their affiliates, successors, transferees, assignees, and the officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf, be permanently enjoined and restrained from in any manner continuing, maintaining, or renewing the conduct, contract, conspiracy or combination alleged herein, or from entering into any other conspiracy alleged herein, or from entering into any other contract, conspiracy or combination having a similar purpose or effect, and from adopting or following any practice, plan, program, or device having a similar purpose or effect;

4. A judgment for Plaintiff and the Class and against Defendants for

damages and, where applicable, treble, multiple, and other damages, including interest on the damages sustained by Plaintiff and the other members of the Class;

5. Plaintiff and each member of the Class recover the amounts by which Defendants have been unjustly enriched;

6. Joint and several judgment be entered against each Defendant in favor of Plaintiff and the other members of the Class;

7. An award to Plaintiff of all costs incurred, including reasonable attorneys' fees; Pre- and post-judgment interest; and

8. Such other and further relief as the Court deems just and proper.

Dated: September 10, 2010 HOLZER HOLZER &FISTEL, LLC

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